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8 Attorneys for Plaintiffs

9 **IN THE UNITED STATES DISTRICT COURT**

10 **DISTRICT OF CALIFORNIA**

11 **DIANE KNIGHT and MORGAN KNIGHT,**
12 **wife and husband,**

13 **Plaintiffs,**

14 **vs.**

15 **ELI LILLY AND COMPANY, an Indiana**
16 **corporation,**

17 **Defendant.**

Cause No.: _____

COMPLAINT
-AND-
DEMAND FOR JURY TRIAL

18 Plaintiffs allege as follows:

19 **PARTIES AND JURISDICTION**

20 1. Subject matter jurisdiction is founded on diversity of citizenship and amount in
21 controversy.

22 2. Plaintiffs Diane Knight and Morgan Knight, wife and husband, are citizens of the
23 State of California, residing and domiciled in San Diego County, California.

24 3. Plaintiff Diane Knight was prescribed with and ingested the prescription medication
25 Zyprexa® (olanzapine) (hereinafter, "Zyprexa"), and suffered personal injuries as a result thereof
26 in the Southern District of California.

27 4. For purposes of this Complaint, unless otherwise specified all references to Plaintiff
28 and/or Plaintiffs refer to Plaintiff Diane Knight.

5. Defendant Eli Lilly and Company ("Lilly") is a corporation domiciled in the State of
Indiana, with a principal place of business at Lilly Corporate Center, in the City of Indianapolis,

FILED

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CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

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1 County of Marion, State of Indiana.

2 6. The matter in controversy, exclusive of interest and costs, exceeds the sum specified
3 in 28 U.S.C. § 1332.

4 7. There is complete diversity of citizenship.

5 **GENERAL ALLEGATIONS**

6 8. At all times relevant herein, Lilly was in the business of designing, testing,
7 manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals,
8 including Zyprexa, and other products for use by the mainstream public, including Plaintiff.

9 9. Zyprexa was manufactured, marketed, distributed and sold to Plaintiff by Lilly and/or
10 Lilly's representatives.

11 10. In September 1996 Lilly obtained approval from the U.S. Food and Drug
12 Administration (hereinafter the "FDA") to market Zyprexa for treatment of adults with schizophrenia
13 with a target dosage of 10 mg/d. In 2001, Zyprexa updated its labeling to include a newly approved
14 indication for the short-term treatment of acute manic episodes associated with Bipolar I Disorder
15 with recommended doses of 10-20 mg/d. Zyprexa has never been indicated for the treatment of
16 children for any purpose.

17 11. Despite its limited approval for marketing, in eight years Zyprexa has become the
18 third-best selling drug in the world. Zyprexa's worldwide sales in 1997, its first full year on the
19 market were \$500 million. According to Lilly's Form 10K, 2004 worldwide Zyprexa sales exceeded
20 \$4.4 billion, which made Zyprexa Lilly's top selling drug by over \$3.2 billion.

21 12. Lilly's own pre-clinical studies regarding Zyprexa and medical literature related to
22 antipsychotic drugs dating to the 1950s demonstrate that Zyprexa and other antipsychotics cause
23 weight gain and hyperglycemia. Further, immediately after Zyprexa's release, Lilly became aware
24 of large numbers of adverse event reports ("AERs") on file with the FDA's Medwatch database
25 involving diabetes-related illnesses associated with the use of Zyprexa. Specifically, there were 200
26 AERs after two years of marketing, 400 AERs after three years and nearly 600 diabetes-related AERs
27 in Zyprexa's fourth year of marketing, all of which were reported to the FDA and known to Lilly.

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1 Additional evidence that Lilly knew of Zyprexa's propensity to cause diabetes and yet failed to
2 adequately warn physicians and patients, including Plaintiffs, is the fact that in April 2002, nearly
3 a year and a half before it first warned of the risk of diabetes in the United States, Lilly changed its
4 labeling in the United Kingdom and Japan to include warnings regarding the association between
5 the use of Zyprexa and diabetes-related injuries. Lilly has been required to revise the labeling of
6 Zyprexa seventeen times since its introduction to the market.

7 13. On September 11, 2003, the FDA informed all manufacturers of atypical
8 antipsychotic drugs, including Lilly, that due to an increasing prevalence of diabetes-related illnesses
9 associated with this class of drugs, that all labeling must bear the following language in the Warnings
10 section:

11 Hyperglycemia, in some cases extreme and associated with
12 ketoacidosis or hyperosmolar coma or death, has been reported in
13 patients treated with atypical antipsychotics. Assessment of the
14 relationship between atypical antipsychotic use and glucose
15 abnormalities is complicated by the possibility of an increased
16 background risk of diabetes mellitus in patients with schizophrenia
17 and the increasing incidence of diabetes mellitus in the general
18 population. Given these confounders, the relationship between
19 atypical antipsychotic use and hyperglycemia-related adverse events
20 is not completely understood. However, epidemiologic studies
21 suggest an increased risk of treatment emergent
22 hyperglycemia-related adverse events in patients treated with atypical
23 antipsychotics. Precise risk estimates for hyperglycemia-related
24 adverse events in patients treated with atypical antipsychotics are not
25 available.

26 Patients with an established diagnosis of diabetes mellitus who are
27 started on atypical antipsychotics should be monitored regularly for
28 worsening of glucose control. Patients with risk factors for diabetes
mellitus (e.g., obesity, family history of diabetes) who are starting
treatment with atypical antipsychotics should undergo fasting blood
glucose testing at the beginning of treatment and periodically during
treatment. Any patient treated with atypical antipsychotics should be
monitored for symptoms of hyperglycemia including polydipsia,
polyuria, polyphagia, and weakness. Patients who develop symptoms
of hyperglycemia during treatment with atypical antipsychotics
should undergo fasting blood glucose testing. In some cases,
hyperglycemia has resolved when the atypical antipsychotic was
discontinued; however, some patients required continuation of
anti-diabetic treatment despite discontinuation of the suspect drug.

14. Despite the FDA's mandate that Lilly immediately warn of the dangers described
above, Lilly waited an additional six (6) months, until March 1, 2004, to send prescribing physicians

1 a "Dear Doctor Letter" advising of the new warnings. Further, the foregoing warning did not appear
2 in the Physicians' Desk Reference until the 2005 edition.

3 15. In March 2004, the U.S. Attorney for the Eastern District of Pennsylvania commenced
4 an investigation into Lilly's marketing practices concerning Zyprexa. Lilly has also received a grand
5 jury subpoena from the Office of Consumer Litigation, Department of Justice, concerning the
6 marketing and promotional practices with respect to a different Lilly drug.

7 16. Under applicable statutes and regulations, the manufacturer of a prescription drug
8 regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other
9 than those approved by the FDA. Uses of a prescription drug for purposes other than those approved
10 by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses
11 of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the
12 United States Government.

13 17. Upon information and belief, Lilly promoted the drugs taken by Plaintiff by
14 employing the illegal direct solicitation of physicians for off-label uses and making false statements
15 to physicians and pharmacists concerning the efficacy and safety of Zyprexa for off-label uses. As
16 a result of Lilly's illegal schemes, Plaintiff was prescribed Zyprexa for an unnecessary and/or
17 off-label use.

18 18. There is no valid scientific evidence to support the contention that Zyprexa is safe and
19 effective for treatment of any off-label use, including any use in children. There is no valid scientific
20 evidence concerning the therapeutic equivalence of Zyprexa for any off-label use, including any use
21 in children.

22 19. Lilly did business in the State of California; made contracts to be performed in whole
23 or in part in California and/or manufactured, tested, sold, offered for sale, supplied or placed in the
24 stream of commerce, or in the course of business materially participated with others in so doing,
25 Zyprexa, which Lilly knew to be defective, unreasonably dangerous and hazardous, and which Lilly
26 knew would be substantially certain to cause injury to persons within the State of California thereby
27 negligently and intentionally causing injury to persons within California, and as described herein,
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1 committed and continues to commit tortious and other unlawful acts in the State of California.

2 20. Lilly sold or aided and abetted in the sale of Zyprexa which was and is defective and
3 unreasonably dangerous. At all pertinent times, Lilly knew, or should have known, that Zyprexa was
4 and is hazardous to human health.

5 21. Lilly, through its funding and control of certain studies concerning the effects of
6 Zyprexa on human health, their control over trade publications, promoting, marketing, and/or
7 through other agreements, understandings and joint undertakings and enterprises, conspired with,
8 cooperated with and/or assisted in the wrongful suppression, active concealment and/or
9 misrepresentation of the true relationship between Zyprexa and various diseases, all to the detriment
10 of the public health, safety and welfare and thereby causing harm to the State.

11 22. Specifically, and in addition to the allegations above, Lilly knew of the hazards
12 associated with Zyprexa; affirmatively and actively concealed information which clearly
13 demonstrated the dangers of Zyprexa and affirmatively misled the public and prescribing physicians
14 with regard to the material and clear risks of Zyprexa; they did so with the intent that prescribing
15 physicians would continue to prescribe Zyprexa; they then well knew that prescribing physicians
16 would not be in a position to know the true risks of Zyprexa; and they knew that prescribing
17 physicians would rely upon the misleading information that they promulgated.

18 23. At all pertinent times, Lilly purposefully and intentionally engaged in these activities,
19 and continues to do so, knowing full well that when the general public, including Plaintiff, uses
20 Zyprexa as Lilly intended, that Plaintiff would be substantially certain to suffer disease, injury and
21 sickness.

22 24. The statements, representations and promotional schemes publicized by Lilly were
23 deceptive, false, incomplete, misleading and untrue. Lilly knew, or should have known, that its
24 statements, representations and advertisements were deceptive, false, incomplete, misleading and
25 untrue at the time of making such statements. Lilly had an economic interest in making such
26 statements. Neither the Plaintiff nor the physicians in California who prescribed Zyprexa had
27 knowledge of the falsity or untruth of Lilly's statements, representations and advertisements when
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1 prescriptions for Zyprexa were written; moreover, the Plaintiff and the Plaintiff's physician had a
2 right to rely on Lilly's statements, representations and advertisements. Each of the statements,
3 representations and advertisements were material to the Plaintiff's purchase of Zyprexa in that the
4 Plaintiff would not have purchased Zyprexa if Plaintiff had known that Lilly's statements,
5 representations and advertisements were deceptive, false, incomplete, misleading and untrue. These
6 acts were designed to and did allow Lilly to earn substantial income from the sale of Zyprexa.

7 25. Plaintiff had a right to rely upon the representations of Lilly and were directly and
8 proximately injured by such reliance, all as described above.

9 26. Had Plaintiff been adequately warned of the potential life-threatening side effects,
10 he/she could have chosen to request other prescription medications and avoided Zyprexa's potential
11 life-threatening side effects.

12 27. Plaintiff were prescribed Zyprexa by physicians authorized to prescribe Zyprexa,
13 ingested Zyprexa as prescribed, and as a result suffered damages and injury.

14 28. Lilly negligently, recklessly and wantonly failed to warn Plaintiff and the general
15 public, of the risks associated with taking Zyprexa. Lilly failed to do so even after various studies,
16 including their own, showed that there were problems concerning the risks of diabetes and
17 diabetes-related injuries associated with Zyprexa.

18 29. Lilly endeavored to deceive Plaintiff, and the general public, by not disclosing the
19 findings of the various studies, including its own, that revealed problems concerning the dangers of
20 Zyprexa.

21 30. Further, Lilly did not provide warnings and instructions that would have put Plaintiff,
22 and the general public, on notice of the dangers and adverse effects caused by Zyprexa.

23 31. Lilly designed, manufactured, distributed, sold and/or supplied Zyprexa into the
24 stream of commerce in a defective and unreasonably dangerous condition, taking into consideration
25 the utility of the drug and the risk to Plaintiff and the general public.

26 32. Zyprexa as designed, manufactured, distributed, sold and/or supplied by Lilly was
27 defective as marketed due to inadequate warnings, instructions and/or labeling.

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33. Zyprexa as designed, manufactured, distributed, sold and/or supplied by Lilly was defective due to inadequate testing before and after Lilly's knowledge of the various studies, including their own, evidencing the rightful concerns over the risks of diabetes and diabetes-related injuries associated with Zyprexa.

COUNT ONE

(STRICT PRODUCTS LIABILITY)

34. Lilly is liable as the manufacturer, distributor and/or seller of the drug Zyprexa because Zyprexa, when sold, was in a defective and unreasonably dangerous condition. Lilly owed a strict duty to Plaintiff not to harm him/her through the use of the drug Zyprexa.

A. DESIGN DEFECT

35. Zyprexa was defective in design and/or formulation in that, when it left the hands of Lilly and/or its representatives, the foreseeable risks of serious harm posed by the drug outweighed its alleged benefits. The foreseeable risks of serious harm were so great that Plaintiff, and the general public, having known of such foreseeable risks and alleged benefits, would not have ingested Zyprexa.

36. Zyprexa was placed into the stream of commerce by Lilly acting through authorized agents, servants, employees and/or representatives. Plaintiff was prescribed Zyprexa by her physician and used the drug in a manner reasonably foreseeable by Lilly.

37. The Zyprexa ingested by Plaintiff was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. As a result of the use of Zyprexa, Plaintiff suffered severe, permanent and disabling injuries and related damages.

B. MARKETING DEFECT-INADEQUATE AND IMPROPER WARNINGS

38. Zyprexa was marketed to physicians to be prescribed to their patients and was marketed and advertised directly to the consuming public. Zyprexa, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks of ingesting the drug. Further, Lilly failed to warn of these serious risks after Lilly

1 had knowledge of same. The information provided to consumers did not reflect Lilly's knowledge
2 that Zyprexa was not safe and effective as indicated in its aggressive marketing campaign, nor were
3 consumers made aware that ingesting the drug could result in serious injury, pain and discomfort
4 and/or death. Full and proper warnings that accurately and fully reflected the risks of serious injury
5 and/or sudden death due to the ingestion of Zyprexa should have been disclosed by Lilly.

6 39. Plaintiff was prescribed Zyprexa by her physician, and used the drug in a manner
7 reasonably foreseeable by Lilly. Zyprexa was expected to and did reach Plaintiff without substantial
8 change in its condition as tested, manufactured, designed, labeled, packaged, marketed and
9 distributed. Plaintiff was not aware of, and could not have reasonably discovered, the unreasonably
10 dangerous nature of Zyprexa.

11 40. At all times herein mentioned, Defendant had an obligation not to violate the law, in
12 the manufacture, design, formulation, compounding, testing, production, processing, assembly,
13 inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and
14 warning of the risks and dangers of the aforementioned products.

15 41. At all times herein mentioned, Defendant violated the Federal Food, Drug and
16 Cosmetic Act, 21 U.S.C. Section 301, et seq., related amendments and codes and federal regulations
17 provided thereunder, the Sherman Food, Drug and Cosmetic Law, California Health and Safety Code
18 Sections 110290, 110390, 110395, 110398, 110400 and 111330, formerly Sections 1750, 1790, et
19 seq., and regulations promulgated thereunder, and other applicable laws, statutes and regulations.

20 42. Plaintiff, as a purchaser and consumer of Zyprexa, is within the class of persons the
21 statutes and regulations described above are designed to protect, and Plaintiff's injuries are the type
22 of harm these statutes are designed to prevent.

23 43. Defendant failed to meet the standard of care set by the following statutes and
24 regulations, which were intended for the benefit of individuals such as Plaintiff, making Defendant
25 negligent per se:

- 26 a. The labeling lacked adequate information on the use of Zyprexa, even though
27 the Defendants were aware of the widespread use of Zyprexa. [21 C.F.R.
28

1 Section 201.56(a) and (d)].

- 2 b. The labeling lacked adequate information on the approximate kind, degree
3 and duration of expected improvement, alone or in combination in violation
4 of 21 C.F.R. 201.57(c)(3)(i).
- 5 c. The labeling did not state that there was a lack of evidence to support the
6 common belief of the safety and advocacy of Zyprexa [21 C.F.R.
7 201.57(c)(3)(i) and (iv) and (c)(2)].
- 8 d. The labeling failed to add warnings for serious cardiovascular, and
9 cerebrovascular events and death as soon as there was reasonable evidence
10 of their association with the drug [21 C.F.R. 201.57(e)].
- 11 e. There was inadequate information for patients for the safe and effective use
12 of Defendant's drugs, in violation of 21 C.F.R. 201.57(f)(2).
- 13 f. There was inadequate information regarding special care to be exercised by
14 the doctor for safe and effective use of Defendant's drugs in violation of 21
15 C.F.R. 201.57(f)(1).
- 16 g. The labeling was misleading and promotional in violation of 21 C.F.R.
17 201.56(b).
- 18 h. The labeling was misleading in violation of California Health and Safety
19 Code Sections 11130 and 110290.
- 20 i. Defendant's advertising and representations regarding the subject drug
21 product were false and misleading in violation of Health and Safety Code
22 Sections 110390 and 110290, and Civil Code Section 1770(a)(5).
- 23 j. There was a failure to warn and/or consult as required by California Code of
24 Regulations § 1707.2.

25 44. As the producing cause and legal and direct result of the failure to warn consumers
26 of the defective condition of Zyprexa, as manufactured and/or supplied by Lilly and its
27 representatives, Plaintiff has suffered severe, permanent and disabling injuries and related damages.
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COUNT TWO

(COMMON LAW FRAUD)

45. Lilly made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Lilly had in its possession adverse drug event reports, drug studies, and other documentation about Zyprexa and yet made the following misrepresentations:

- a. Misrepresented the frequency of Zyprexa-related adverse event reports or occurrences in the Zyprexa label, package insert or PDR label;
- b. Misrepresented the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Zyprexa;
- c. Misrepresented the efficacy of Zyprexa;
- d. Misrepresented the number of adverse events and deaths reported with the use of Zyprexa;
- e. Misrepresented the nature, seriousness, and severity of adverse events reported with the use of Zyprexa.
- f. Lilly's misrepresentations were the proximate and/or producing cause of Plaintiff's injuries.

46. Plaintiff had a right to, and did rely, upon those, and other material misrepresentations.

47. Lilly intended that these misrepresentations be relied upon by physicians, including Plaintiff's physician, healthcare providers and consumers.

48. Plaintiff did rely upon the misrepresentations that caused her injuries.

COUNT THREE

(NEGLIGENCE)

49. Lilly owed Plaintiff a legal duty in connection with its development, manufacture, and distribution of Zyprexa. Lilly breached those duties, proximately causing Plaintiff's injuries. Specifically, Lilly failed to meet its duty to use reasonable care in the testing, creating, designing,

1 manufacturing, labeling, packaging, marketing, selling, and warning of Zyprexa. Lilly is liable for
2 acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not
3 limited to the following:

- 4 a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known
5 or reasonably foreseeable danger that Plaintiff would suffer a serious injury
6 or death by ingesting Zyprexa;
- 7 b. Failure to adequately warn Plaintiff and Plaintiff's physician of the known or
8 reasonably foreseeable danger that Plaintiff would suffer a serious injury or
9 death by ingesting Zyprexa in unsafe doses;
- 10 c. Failure to use reasonable care in testing and inspecting Zyprexa so as to
11 ascertain whether or not it was safe for the purpose for which it was designed,
12 manufactured and sold;
- 13 d. Failure to use reasonable care in implementing and/or utilizing a reasonably
14 safe design in the manufacture of Zyprexa;
- 15 e. Failure to use reasonable care in the process of manufacturing Zyprexa in a
16 reasonably safe condition for the use for which it was intended;
- 17 f. Failure to use reasonable care in the manner and method of warning Plaintiff
18 and Plaintiff's physicians as to the danger and risks of using Zyprexa in
19 unsafe doses;
- 20 g. Such further acts and/or omissions that may be proven at trial.

21 50. The above-described acts and/or omissions of Lilly were a direct and proximate cause
22 of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

23 **COUNT FOUR**

24 **(NEGLIGENT MISREPRESENTATION)**

25 51. Lilly failed to communicate to Plaintiff and/or the general public that the ingestion
26 of Zyprexa could cause serious injuries after it became aware of such risks. Instead, Lilly
27 represented in its marketing that Zyprexa was safe and effective.
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a. Lilly, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Zyprexa in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Lilly made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

9 b. The above misrepresentations were made to Plaintiff, as well as the general
0 public;

c. Plaintiff and their healthcare providers justifiably relied on Lilly's misrepresentations; and

d. Consequently, Plaintiff ingested Zyprexa to her detriment. Lilly's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

5 **COUNT FIVE**
6 **(MISREPRESENTATION)**

53. Lilly is engaged in the business of selling Zyprexa. By its advertising, labels, or otherwise, Lilly has made to Plaintiffs, and the public, misrepresentations of material fact concerning the character or quality of Zyprexa.

54. Plaintiff justifiably relied on Lilly's misrepresentations in purchasing Zyprexa. Plaintiff has suffered physical harm proximately caused by Lilly's misrepresentations regarding the character or quality of Zyprexa.

COUNT SIX

(EXPRESS WARRANTY)

55. Lilly is a merchant and/or seller of Zyprexa. Lilly sold Zyprexa to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Lilly made representations to Plaintiff about the quality or characteristics of Zyprexa by affirmation of fact,

1 promise and/or description.

2 56. The representations by Lilly became part of the basis of the bargain between Lilly and
3 Plaintiff. Zyprexa did not comport with the representations made by Lilly in that it was not safe for
4 the use for which it was marketed. This breach of duty by Lilly was a proximate cause of the injuries
5 and monetary loss suffered by Plaintiff.

6 **COUNT SEVEN**

7 **(IMPLIED WARRANTY)**

8 **A. WARRANTY OF MERCHANTABILITY**

9 57. Lilly is a merchant and/or seller of Zyprexa. Plaintiff purchased Zyprexa from Lilly
10 and used Zyprexa for the ordinary purpose for which it is used by consumers. At the time it was
11 purchased by Plaintiff, Zyprexa was not fit for the ordinary purpose for which such drugs are used.
12 Zyprexa was not fit for the ordinary purpose for which such drugs are used because it was not
13 manufactured, designed or marketed in a manner to accomplish its purpose safely. Lilly's breach
14 of its implied warranty of merchantability caused Plaintiff's injuries and monetary losses.

15 **B. WARRANTY OF FITNESS**

16 58. Lilly sold Zyprexa to Plaintiff with the knowledge that Plaintiff was purchasing
17 Zyprexa for a particular purpose. Further, Lilly knew, or should have known, that Plaintiff was
18 justifiably relying on Lilly's skill or judgment to select goods fit for Plaintiff's purpose.

19 59. Lilly delivered goods that were unfit for Plaintiff's particular purpose, and thus
20 breached its implied warranty of fitness.

21 60. Lilly's failure to select and sell a product which was reasonably safe for its intended
22 use proximately caused Plaintiff's injuries and monetary losses.

23 **COUNT EIGHT**

24 **(VIOLATION OF BUSINESS & PROFESSION CODE SECTION 17200)**

25 61. Plaintiffs are informed and believe and allege that Defendant, by the acts and
26 misconduct alleged herein, violated Business and Professions Code sections 17200.

27 62. California Business & Professions Code Section 17200 provides that unfair
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1 competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair,
2 deceptive, untrue or misleading advertising."

3 63. The acts and practices described herein were and are likely to mislead the general
4 public and therefore constitute unfair business practices within the meaning of Business &
5 Professions Code Section 17200. The acts and untrue and misleading advertising set forth in
6 presiding paragraphs are incorporated by reference and are, by definition, violations of Business &
7 Professions Code Section 17200. This conduct includes, but is not limited to:

- 8 a. Representing to Plaintiff, Plaintiff's physician and the general public that
9 Zyprexa was safe, fit and effective for human consumption, knowing that said
10 representations were false, and concealing from the Plaintiff, Plaintiff's
11 physician and the general public that Zyprexa has a serious propensity to
12 cause injuries to users;
- 13 b. Engaging in advertising programs designed to create the image, impression
14 and belief by consumers, physicians and others that the use of Zyprexa was
15 safe for human use, had fewer side effects and adverse reactions than other
16 methods for treating mental illness, constituted a convenient, safe form for
17 treating mental illness and would not interfere with daily life, even though the
18 Defendant knew these to be false, and even though the Defendant had no
19 reasonable grounds to believe them to be true;
- 20 c. Purposely downplaying and understating the health hazards and risks
21 associated with Zyprexa; and
- 22 d. Issuing promotional literature deceiving potential users of Zyprexa by
23 relaying positive information and manipulating statistics to suggest
24 widespread acceptability, while downplaying the known adverse and serious
25 health effects and concealing material relevant information regarding the
26 safety of Zyprexa.

27 64. These practices constitute unlawful, unfair and fraudulent business acts or practices,
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1 within the meaning of California Business & Professions Code Section 17200, as well as unfair,
2 deceptive, untrue and misleading advertising as prohibited by California Business & Professions
3 Code Section 17500, as set forth herein.

4 65. The unlawful, unfair and fraudulent business practices of Defendant described above
5 present a continuing threat to members of the public in that Defendant continue to engage in the
6 conduct described therein.

7 66. As a result of their conduct described above, Defendant have been unjustly enriched.
8 Specifically, Defendant have been unjustly enriched by receipt of hundreds of millions of dollars in
9 ill-gotten gains from the sale and prescription of Zyprexa in California, and other states, sold in large
10 part as a result of the acts and omissions described herein.

11 67. Because of the fraudulent misrepresentations made by Defendant as detailed above,
12 and the inherently unfair practice of committing a fraud against the Plaintiffs and public by
13 intentionally misrepresenting and concealing material information, the acts of Defendant described
14 herein constitute unfair or fraudulent business practices.

15 68. Plaintiffs, pursuant to California Business & Professions Code Section 17203, seek
16 an order of this court compelling the Defendant to provide restitution, and to disgorge the monies
17 collected and profits realized by Defendant, and each of them, as a result of their unfair business
18 practices.

19 69. Defendant's acts were willful, wanton, reckless and fraudulent; hence, Plaintiffs are
20 entitled to exemplary damages, *inter alia*.

21 **COUNT NINE**

22 **(VIOLATION OF BUSINESS & PROFESSION CODE SECTION 17500)**

23 70. Plaintiffs are informed and believe and thereon allege that Defendant, by the acts and
24 misconduct alleged herein, violated Business & Professions Code Section 17500.

25 71. On behalf of the general public, Plaintiffs hereby seek restitution, as well as punitive
26 damages against Defendant for its violations of section 17500.

27 72. California Business & Professions Code section 17500 provides that it is unlawful
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1 for any person, firm, corporation or association to dispose of property or perform services, or to
2 induce the public to enter into any obligation relating thereto, through the use of untrue or misleading
3 statements.

4 73. At all times herein mentioned, Defendant has committed the acts of disseminating
5 untrue and misleading statements as defined by Business & Professions Code Section 17500 by
6 engaging in the following acts and practices with intent to induce members of the public to purchase
7 and use Zyprexa:

- 8 a. Representing to Plaintiff, Plaintiff's physicians and the general public that
9 Zyprexa was safe, fit and effective for human consumption, knowing that said
10 representations were false, and concealing from the Plaintiff, Plaintiff's
11 physicians and the general public that Zyprexa have a serious propensity to
12 cause injuries to users;
- 13 b. Engaging in advertising programs designed to create the image, impression
14 and belief by consumers, physicians and others that the use of Zyprexa was
15 safe for human use, had fewer side effects and adverse reactions than other
16 methods for treating mental illness, constituted a convenient, safe form for
17 treating mental illness and would not interfere with daily life, even though the
18 Defendant knew these to be false, and even though the Defendant had no
19 reasonable grounds to believe them to be true;
- 20 c. Purposely downplaying and understating the health hazards and risks
21 associated with Zyprexa; and
- 22 d. Issuing promotional literature deceiving potential users of Zyprexa by
23 relaying positive information and manipulating statistics to suggest
24 widespread acceptability, while downplaying the known adverse and serious
25 health effects and concealing material relevant information regarding the
26 safety of Zyprexa.

27 74. The foregoing practices constitute false and misleading advertising within the
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1 meaning of California Business & Professions Code Section 17500.

2 75. As a result of its false and misleading statements described above, Defendant has
3 been and will be unjustly enriched. Specifically, Defendant has been unjustly enriched by receipt
4 of hundreds of millions of dollars from the sale and prescription of Zyprexa in California and other
5 states, sold in large part as a result of the false or misleading statements described herein.

6 76. Pursuant to California Business & Professions Code Section 17535, Plaintiffs seek
7 an order of this court compelling the Defendant to provide restitution, and to disgorge the monies
8 collected and profits realized by Defendant, and each of them, as a result of their unfair business
9 practices, and injunctive relief calling for Defendant to cease such unfair business practices in the
10 future.

11 77. Plaintiffs seek punitive damages, restitution and disgorgement of the monies collected
12 and profits realized by Defendant as a result of its false and misleading advertising.

13 **COUNT TEN**

14 **(LOST CONSORTIUM)**

15 78. Plaintiffs also claim a loss of consortium.

16 **DAMAGES**

17 79. Upon the trial of this case, it will be shown that Plaintiffs were caused to sustain
18 serious injuries and damages as a proximate result of Lilly's conduct. These damages include, but
19 are not limited to, medical bills and associated expenses, lost earning capacity, lost income, lost love
20 and affection, pain, suffering and other special, general and consequential damages. Plaintiffs will
21 respectfully request the Court and Jury to determine the amount of the loss Plaintiffs have incurred
22 in the past and will incur in the future, not only from a financial standpoint, but also in terms of good
23 health and freedom from pain and worry.

24 **PUNITIVE DAMAGES**

25 80. At all times relevant hereto, Lilly actually knew of the defective nature of Zyprexa
26 as set forth herein and continued to design, manufacture, market, distribute and sell Zyprexa so as
27 to maximize sales and profits at the expense of the public's health and safety and in conscious
28

1 disregard of the foreseeable serious harm caused by Zyprexa. Lilly's conduct exhibits such an entire
 2 want of care as to establish that its actions were a result of fraud, ill will, recklessness, and/or willful
 3 and intentional disregard for the safety and rights of Plaintiffs, as well as the general public and/or
 4 consumers of Zyprexa. Further, this conduct was pursued even though Lilly knew there was a
 5 substantial risk their actions would result in significant harm to Plaintiffs. This conduct is
 6 outrageous and Plaintiffs are therefore entitled to punitive damages.

7 WHEREFORE, Plaintiffs pray for judgment against Defendant, and each of them, as
 8 follows:

- 9 a. Past, present, and future special damages;
- 10 b. Past, present, and future general damages;
- 11 c. Punitive damages;
- 12 d. Restitution;
- 13 e. Disgorgement of profits;
- 14 f. Prejudgment interest;
- 15 g. Costs and attorneys' fees; and
- 16 h. Such other and further relief as the court deems just and proper.

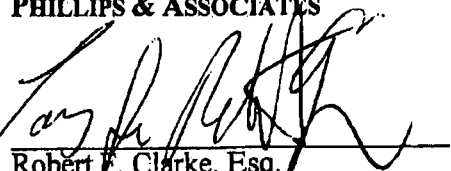
17 **JURY DEMAND**

18 Plaintiffs, pursuant to the Federal Rules of Civil Procedure and all applicable local rules of
 19 Court, demand a trial by jury.

20 **RESPECTFULLY SUBMITTED** this ____ day of June, 2008.

21 **PHILLIPS & ASSOCIATES**

22
 23 By


 Robert F. Clarke, Esq.
 3030 North Third Street, Suite 1100
 Phoenix, Arizona 85012
 Attorneys for Plaintiffs

"VIA FAX"

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS Knight, Diane; Knight, Morgan (b) County of Residence of First Listed Plaintiff <u>San Diego</u> (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorney's (Firm Name, Address, and Telephone Number) Robert F. Clarke, Phillips & Associates, 3030 N Third St, Ste 1100, Phoenix, AZ 85012; Tel: (602) 258-8900	DEFENDANTS Eli Lilly and Company <div style="text-align: right; font-size: 1.2em;">08 JUN 17 PM 3:24</div> <div style="text-align: right; font-size: 0.8em;">CLERK, U.S. DISTRICT COURT SOUTHERN DISTRICT OF CALIF. IN 2</div> County of Residence of First Listed Defendant <u>EC</u> (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED. BY: <u>DEPUTY</u> Attorneys (If Known) <u>08 CV 1075 BEN CAB</u>
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II. BASIS OF JURISDICTION (Place an "X" in One Box Only) <input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) <table style="width: 100%;"> <tr> <td style="width: 50%;"> Citizen of This State <input checked="" type="checkbox"/> 1 Citizen of Another State <input type="checkbox"/> 2 Citizen or Subject of a Foreign Country <input type="checkbox"/> 3 </td> <td style="width: 50%;"> DEF <input type="checkbox"/> 1 Incorporated or Principal Place of Business in This State <input type="checkbox"/> 4 Incorporated and Principal Place of Business in Another State <input checked="" type="checkbox"/> 5 Foreign Nation <input type="checkbox"/> 6 </td> </tr> </table>	Citizen of This State <input checked="" type="checkbox"/> 1 Citizen of Another State <input type="checkbox"/> 2 Citizen or Subject of a Foreign Country <input type="checkbox"/> 3	DEF <input type="checkbox"/> 1 Incorporated or Principal Place of Business in This State <input type="checkbox"/> 4 Incorporated and Principal Place of Business in Another State <input checked="" type="checkbox"/> 5 Foreign Nation <input type="checkbox"/> 6
Citizen of This State <input checked="" type="checkbox"/> 1 Citizen of Another State <input type="checkbox"/> 2 Citizen or Subject of a Foreign Country <input type="checkbox"/> 3	DEF <input type="checkbox"/> 1 Incorporated or Principal Place of Business in This State <input type="checkbox"/> 4 Incorporated and Principal Place of Business in Another State <input checked="" type="checkbox"/> 5 Foreign Nation <input type="checkbox"/> 6		

IV. NATURE OF SUIT (Place an "X" in One Box Only)					
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) PROXY TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

V. ORIGIN (Place an "X" in One Box Only)						
<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from another district (specify)	<input type="checkbox"/> 6 Multidistrict Litigation	<input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): <u>Diversity 28 U.S.C. § 1332</u>
	Brief description of cause: <u>Personal injuries arising from ingestion of prescription medication Zyprexa, a defective drug.</u>

VII. REQUESTED IN COMPLAINT:	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
	DEMAND \$ _____ JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

VIII. RELATED CASE(S) IF ANY	(See instructions): JUDGE <u>Hon. Jack B. Weinstein (E.D.N.Y.)</u>	DOCKET NUMBER <u>04-MDL-1596</u>
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DATE <u>06/16/2008</u>	SIGNATURE OF ATTORNEY OF RECORD
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FOR OFFICE USE ONLY	RECEIPT # <u>152024</u>	AMOUNT <u>\$ 350.00</u>	APPLYING IFP _____	JUDGE _____	MAG. JUDGE _____
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TAL 6/17/08

CR

JS 44 Reverse (Rev. 12/07)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**Authority For Civil Cover Sheet**

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.**

Example:

U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

**UNITED STATES
DISTRICT COURT**
SOUTHERN DISTRICT OF CALIFORNIA
SAN DIEGO DIVISION

152024 - TC
* * C O P Y * *
June 17, 2008
15:24:18

Civ Fil Non-Pris

USAO #.: 08CV1075
Judge.: ROGER T BENITEZ
Amount.: \$350.00 CK
Check#.: BC10622

Total-> \$350.00

FROM: DIANE & MORGAN KNIGHT
VS.
ELI LILLY & CO.